

K061094

JUL 28 2006

**ATTACHMENT 3, page 22**  
**510(k) SUMMARY**

**A. Sponsor**

Newport Medical Instruments, Inc.

1620 Sunflower Ave

Costa Mesa, California 92626

Telephone: (714) 427-5811

Fax: (714) 427-0839

Contact Person: Richard Waters

Vice President, Regulatory Affairs & Quality Assurance

**B. Date Prepared**

4/18/2006

**C. Device Name**

Trade Name: Newport e500 Wave Ventilator

Classification Name: Continuous Ventilator

**D. Device Description**

The Newport e500 Wave Ventilator is a pneumatically powered, microprocessor controlled ventilator cleared through Premarket Notification.

Performance characteristics and clinical features support infant/pediatric (>20 mL) through adult patients.

Front panel controls allow trained operators to select ventilation controls under volume control, pressure control and volume target pressure control breath types in A/CMV, SIMV and SPONT modes.

A comprehensive alarm system is built-in to alert the user to violations of preset safety limits.

The alarms associated with the e500 meet or exceed standards of critical care ventilators and have been developed in compliance with ISO9703-1, ISO9703-2 and EN475. The alarms of the e500 span both technical (ventilator related) alarms and non technical alarms (patient related alarms).

**E. Intended Use**

The e500 Ventilator is intended to provide continuous (ET tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric, and adult patients with a

## **ATTACHMENT 3, page 23**

tidal volume of  $\geq 20$  mL. The device is prescription use only. The intended environments include hospital, hospital-type, and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing facilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility.

### **F. Cleared/Predicate Device**

#### Cleared Device

Newport e500 Ventilator, K030780

#### Predicate Devices

Drager EvitaXL K051263, July 12th, 2005

Maquet Servo-I Ventilator, K041223, July 29th, 2004

Puritan-Bennett 840, K984535, December 28, 1998

### **G. Summary of Substantial Equivalence**

The Newport e500 Wave Ventilator is substantially equivalent to the cleared/predicate devices in intended use, physical characteristics, performance specifications and safety characteristics.

### **H. Testing**

Comprehensive verification and validation testing was performed with the Newport e500 Wave Ventilators including; hardware, software, electrical safety, functional safety, EMC, packaging, and environmental. All test results met pre-defined acceptance criteria.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 28 2006

Mr. Richard Waters  
Vice President, Regulatory Affairs & Quality Assurance  
Newport Medical Instruments, Incorporated  
1620 Sunflower Avenue  
Costa Mesa, California 92626

Re: K061094

Trade/Device Name: Newport e500 Wave Ventilator  
Regulation Number: 21 CFR 868.5895  
Regulation Name: Continuous Ventilator  
Regulatory Class: II  
Product Code: CBK  
Dated: July 12, 2006  
Received: July 13, 2006

Dear Mr. Waters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital.

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**ATTACHMENT 1, page 20**  
**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): \_\_\_\_\_

Device Name: Newport e500 Wave Ventilator

Indications for Use:

The e500 Ventilator is intended to provide continuous (ET tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric, and adult patients with a tidal volume of  $\geq 20$  mL. The device is prescription use only.

The intended environments include hospital, hospital-type, and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing facilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

Augustine  
\_\_\_\_\_  
Director of Anesthesiology, General Hospital,  
Device Control, Dental Devices  
Number K061094